Sklar Corporation
889 South Matlack Street
West Chester, PA 19382
Phone: 610-430-3200
Toll Free: 800-221-2166
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K083479

APR 24 2009

EXHIBIT 1

510(K) SUMMARY

1. **Submitted By:**

Michelle Wirtner, General Counsel
Sklar Corporation (d/b/a Sklar Instruments)
889 South Matlack Street
West Chester, PA 19382
Tel: 800-221-2166
Fax: 610-350-0583

Date Submitted: 8/25/08

2. **Device Names:** **Trade/Proprietary Name:** Sklar Surgical Gown

Common Name: Surgical gown

Classification: Class II, 21 CFR 878.4040
Product Code: FYA (Surgical Apparel)

3. **Predicate Device Information:**

Welmed Inc. Surgical Gowns – K070431

4. **Device Description:**

The Sklar Surgical Gown is an open back gown manufactured from a non-woven fabric. The non-woven fabric is a polypropylene spunbond meltblown and the fibers are mechanically bonded together. The Surgical Gown comes in various sizes without any areas of reinforcement. The Surgical Gowns are supplied sterile and non-sterile, for single use only.

5. **Indications for Use:**

The Sklar Surgical Gown is a single use, sterile or non-sterile item that is intended to be used in the operating room to be a protective covering, for operating room staff, from the transfer of body fluids and particulates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2009

Sklar Corporation
C/o Ms. Natalya Valerio
Mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K082479
Trade/Device Name: Sklar General Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 14, 2009
Received: April 15, 2009

Dear Ms. Valerio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

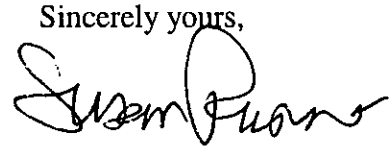
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Sklar General Surgical Gown

Indications For Use:

The Sklar Surgical Gown is a disposable item that is intended to be used in the operating room as a protective covering, for operating room staff, from the transfer of body fluids and particulates.

The Sklar Surgical Gown is provided as sterile and non-sterile.

Sterile gowns are to be sold directly to users following EtO sterilization validation according to ISO 11135-1:2007. Non-sterile gowns are to be sold to OEMs for EtO sterilization according to ISO 11135-1:2007.

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082479